Fact Sheet for Pregnant Women:
Understanding Results from the
Aptima® Zika Virus Assay

June 17, 2016

Dear Madam:

You are being given this Fact Sheet, because your blood was tested for evidence of Zika virus infection. This testing is being done because you have symptoms of Zika virus infection and you live in or have traveled to an area with active Zika virus transmission, or you have a male sex partner who has lived in or traveled to an area with ongoing Zika virus transmission. The test used on your specimen(s) is called the Aptima® Zika Virus assay, which is a laboratory test designed to help detect Zika virus infection in humans.

This Fact Sheet contains information to help you understand the risks and benefits of using the Aptima® Zika Virus assay. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet and any additional questions you may have.

What is Zika virus infection?
Zika virus infection is caused by the Zika virus and is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her unborn baby. Zika virus can also be sexually transmitted by a man to his sexual partners. Since 2015, a large number of Zika virus cases have been reported in many South and Central American countries.

Most people who are infected with Zika virus do not have any symptoms. Those that do, usually have mild illness with symptoms that may include fever, joint pains, rash, or redness of the eyes. These symptoms often resolve on their own within a week.

Although the Centers for Disease Control and Prevention (CDC) is still investigating the potential harms from Zika virus infection, it has concluded that there is enough scientific evidence to state that Zika virus infection during pregnancy is a cause of birth defects (such as microcephaly) and other poor pregnancy outcomes. Zika virus infection in a pregnant woman does not definitely mean she will have pregnancy problems. However, a woman who is infected with Zika virus during pregnancy is at increased risk of miscarriage, having a baby that is stillborn, or having a baby that is small at birth, has incomplete brain development (microcephaly), and/or eye problems. Women who get Zika virus infection while pregnant should be monitored more closely by their health care providers throughout their pregnancy. There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

What is the Aptima® Zika Virus assay?
The Aptima® Zika Virus assay is a laboratory test designed to detect Zika virus. The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why was my sample tested using the Aptima® Zika Virus assay?
You were tested because you have symptoms that resemble Zika virus infection and because you live in or have traveled to an area with active Zika virus transmission or have a male sex partner who has lived in or traveled to an area with active Zika virus transmission. The sample collected from you was tested using the Aptima® Zika Virus assay to help find out whether you may be infected with Zika virus. The test results, along with other information, could help your doctors make decisions about how to take care of you and better monitor your pregnancy.

What are the known and potential risks and benefits of the Aptima® Zika Virus assay?
You may feel discomfort when the sample is taken. There is a very small chance that the test result is incorrect (see next paragraphs for more information). The results of this test, along with other information, can help your health care provider make decisions about how to take care of you and your baby.

If this test is positive for Zika virus, does it mean that I have Zika virus infection?
If you have a positive test, it is very likely that you have a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong; this is called a "false positive" result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself. They will also work closely with you to monitor the health and development of your baby.

If this test is positive for Zika virus, does it mean that my child will have a birth defect?
No, not necessarily. While evidence shows that Zika virus infection during pregnancy is a cause of birth defects and other poor pregnancy outcomes, not all Zika virus infections result in these pregnancy problems. This test result may lead your doctors to follow your pregnancy more closely, however, a Zika virus infection in a mother does not always mean the baby will be harmed.

If this test is negative, does it mean that I do not have Zika virus infection?
A negative test result for the Aptima® Zika Virus assay means that Zika virus was not found in your sample. A negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with Zika virus infection. Most people with Zika virus infection have virus in their blood for up to a week following the start of illness. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people do. It can also happen if your illness/symptoms started earlier than the date you first noticed them. In these cases, the virus may already be gone from your body before the sample is taken for testing.

If your result for the Aptima® Zika Virus assay is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take. Your health care provider will work with you to continue to monitor your health and the health of your baby.

What is an Emergency Use Authorization (EUA)?
An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Aptima® Zika Virus assay, under an EUA.

At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus. FDA has authorized the emergency use of the Aptima® Zika Virus assay to test for the presence of Zika virus in blood specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?
Information about Zika virus is available at the CDC website: http://www.cdc.gov/zika/index.html.
Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Aptima® Zika Virus assay will be made available at the Hologic website: http://www.hologic.com/.

Please also contact your health care provider if you have any questions.